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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,894	11/30/2001	Michael Hutchinson	0922/63690	4202

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EXAMINER

SMITH, RUTH S

ART UNIT PAPER NUMBER

3737

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,894

Applicant(s)

HUTCHINSON, MICHAEL

Examiner

Ruth S. Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 11, 2006 has been entered.

***Specification***

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

***Claim Rejections - 35 USC § 112***

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 1-11, 13, 14, 16 and 17, the specification does not adequately describe how a white matter suppressed (WMS) signal of SNc tissue is used to produce resultant signals indicative of PD or PSP (it appears, rather that WMS of peduncular or crus cerebri regions are obtained). Regarding claims 10 and 11, the specification does not adequately disclose how information is combined from the GMS and WMS images to produce signals indicative of PSP. Regarding claims 12-14, the

specification does not adequately disclose how the MRI images are combined to differentiate between PD and PSP. Regarding claims 15-17, the specification does not adequately describe how the MRI images are combined to identify PSP.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4,9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gosche in view of Hutchinson et al " Parkinson's disease: a novel MRI method for determining structural changes in the substantia nigra" or Hutchinson et al "Structural Changes of the Substantia Nigra in Parkinson's Disease as Revealed by MR Imaging". Gosche discloses a method for detecting a variety of neurological disorders (including Parkinson's) by obtaining volumetric measurements indicative of atrophy due to a pathological process (col. 8 lines 39-58, col. 9 line 66 - col. 10 line 18). Gosche further discloses obtaining a plurality of images and performing segmenting/thresholding (i.e., suppressing) to classify GM, WM, CSF, etc. (e.g., col. 9 lines 33-40). Gosche further discloses using different MRI parameters (col. 11 lines 51-64). Gosche does not

explicitly address SNc tissue and comparing the suppressed white matter and gray matter signals, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to specifically image the substantia nigra in the invention of Gosche when diagnosing a neurological disorder such as Parkinson's as is well known in the art (as per applicants' admission in each of the Hutchinson et al articles). The articles disclose comparing the signals by providing ratios of such. In addition, PD inherently involves a loss from lateral to medial portions of the SNc (as evidenced in article (1) p. 817 and article (2) p. 698, incorporated by reference). Regarding claims 2, 3, 14 and 17, Although Gosche discloses T1 imaging, inversion recovery (IR) pulse sequences are not explicitly addressed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use inversion recovery pulse sequences because Applicant has not disclosed that such sequences provide an advantage, are used for a particular purpose, or solve a stated problem (see e.g., 11 (0013)). One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the multispectral data set based on PD, T1, and T2 sequences of Gosche since both enable WM/GM delineation for detecting neurological atrophy indicative of Parkinson's disease. Regarding claim 4, although Gosche does not explicitly address obtaining a ratio image, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to take a ratio of the different images of Gosche to objectively quantify signals for subsequent comparison/analysis as is well known in the art (as per applicants' admission regarding the Hutchinson et al articles). Regarding claims 10-13, although Gosche does not explicitly address detecting PSP, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect PSP because Applicant has not disclosed that such detection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the detection of PD as taught by Gosche because both are able to diagnose presence and severity of a neurological disorder related to PD (see e.g., Gosche col. 8 lines 51-58 and col. 9 lines 20-26).

### ***Response to Arguments***

Applicant's arguments filed September 11, 2006 have been fully considered but they are not persuasive. Regarding the rejections under 35 USC, 112 first paragraph, essential subject matter cannot be incorporated by reference using non-patent publications. (Applicant's attention is invited to MPEP 608.01 (p)). Applicant's remarks regarding articles 1 and 2 as being applicant's own work is insufficient. Applicant's attention is directed to MPEP 715.01 (c) which states that a declaration must be submitted stating that the articles are applicant's own work.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', with a stylized, cursive script.

Ruth S. Smith  
Primary Examiner  
Art Unit 3737

RSS